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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,318	12/12/2003	Charles E. Lundy	OT01455	2216

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,318	LUNDY ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt is acknowledged of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, the Amendment and Applicant's Arguments/Remarks, all filed 04/27/10.

Claims 1-12 are pending in this action. Claim 1 has been amended herein.

Claims 1-12 are rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 April 2010 has been entered.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. Claim 1 as now amended recites a "single" liner covering said sealing surface…'. The recitation of a "single" liner is a limitation that introduces new matter into the claims. A review of the instant specification establishes that support cannot be found for a "single" liner as now presented. The original specification/disclosure does not support the concept of a structure that is limited to the use of a "single" liner as now recited. The originally filed specification is not restricted to using only a "single" liner and permits the use of more than one liner. Nowhere in the specification does the recitation of a "single" liner occur and the specification fails to support the concept that only a "single" liner must be used. Hence, ample support has not been established for a "single" liner as now presented by Applicant. This is a new matter rejection.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert *et al.* (WO 96/19205) in view of Chiang *et al.* (U.S. Pat. No. 4,973,468) and further in view of Min *et al.* (U.S. Pat. No. 5,916,587).

Ebert *et al.* ('205) teach a transdermal delivery device for administering an active agent to the skin or mucosa of an individual comprising a laminated composite of an adhesive overlay (26), a backing layer (14) underlying the central portion of the adhesive overlay, an active agent-permeable membrane (16), the backing layer and membrane defining a reservoir (12) that contains a formulation of the active agent, a peel seal disc (20) underling the active agent-permeable membrane, a heat seal (22) about the periphery of the peel seal disc the active agent-permeable membrane and the backing layer and a removable release liner (24) underlying the exposed overlay and peel seal disc. The adhesive layer is above and peripheral to the path of the active agent to the skin or mucosa and is protected from degradation by the components of the reservoir by a multiplicity of heat seals. The peel seal disc protects against release of the active agent-containing reservoir and the release liner protects the adhesive from exposure to the environment prior to use (see Abstract) and (page 3, line 24 – pg. 4, line 10).

The formulation contained in the reservoir may include *solvents*, gelling agents, stabilizers, anti-irritants and other additives (p. 8, lines 11-22).

Ebert teaches a membrane layer, which may or may not be a rate-controlling element depending upon the particular drug involved, the permeability of the skin to the drug, and the rate of delivery required to provide therapy (p. 8, line 23 – p. 9, line 2). Ebert teaches the inclusion of microporous membranes, which is equivalent to Applicant's claimed limitation of 'at least one opening in the cover for said reservoir' (p. 9, lines 3-7).

Ebert also teaches fatty acid esters, such as glyceryl monoleate (Example 1- p. 11, line 6).

Ebert does not teach a polymeric thickening agent and a dialkylene glycol alkyl ether, such as dialkylene glycol monoethyl ether.

Chiang *et al.* ('468) teach skin permeation enhancer compositions, which increase the permeability of skin to transdermally administered pharmacologically active agents. The composition contains diethylene glycol monoethyl ether in addition to an ester component such as propylene glycol monolaurate, methyl laurate or the like (see Abstract); (col. 3, lines 8-18; 54-64); (col. 5, line 65- col. 6, line 6). The ether component aids in increasing the skin flux of a selected drug and may act as a solubilizer or vehicle (col. 6, lines 7-17).

The drug/permeation enhancer reservoir may comprise polymeric materials, such as hydrophobic polymers that may serve as thickening agents (col. 6, line 61 – col. 7, line 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate polymeric thickening agents and a dialkylene glycol alkyl ether, such as diethylene glycol monoethyl ether, as taught by Chiang *et al.* within the transdermal device of Ebert *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Chiang *et al.* teach polymeric thickening agents used for their thickening properties and also teach a dialkylene glycol alkyl ether (*i.e.*, diethylene glycol monoethyl ether) that functions to aid in increasing the skin flux of a drug and acts as a solubilizer or vehicle. The expected result would be an enhanced transdermal delivery system for the effective delivery of active agents.

* * * * *

The teachings of Ebert *et al.* are delineated above. Ebert *et al.* do not teach an alkylene glycol, such as propylene glycol.

Min *et al.* ('587) teach a transdermal delivery system comprising solvents, used as an absorption assistant that dissolves active substances, whereby suitable solvents disclosed include propylene glycol (see col. 2, line 66 – col. 3, line 2). Additional solvents disclosed include diethylene glycol monoethyl ether (col. 3, line 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate solvents, such as an alkylene glycol, particularly, propylene glycol as taught by Min *et al.* within the transdermal device of Ebert *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Min *et al.* teach a transdermal delivery system comprising solvents, (i.e., propylene glycol; diethylene glycol monoethyl ether), whereby the solvent (propylene glycol) functions in dissolution of active substances. The expected result would be an improved transdermal delivery system that exhibits enhanced dissolution of active substances.

* * * * *

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert *et al.* (WO 96/19205) as applied to claims 1-7 and 10-12 above and further in view of Toppo (U.S. Pat. No. 5,985,860).

The teachings of Ebert *et al.* are discussed above. Ebert *et al.* do not teach an active agent being salicylic acid.

Toppo ('860) teaches a transdermal delivery system comprising pain-relieving substances (see Abstract). Suitable and effective pain relieving medicaments disclosed include salicylic acid (see column 3, lines 29-35) and Claim 9.

Example twenty (20) at column 8, lines 31-51 demonstrates preparation of a transdermal solution containing 6% by weight of salicylic acid. ((This amount reads on Applicant's claimed range of from about 5% to about 40% by weight of salicylic acid (claim 9)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate active agents, such as salicylic acid as taught by Toppo within the transdermal device of Ebert *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Toppo teaches a transdermal delivery system comprising pain-relieving medicaments, such as salicylic acid and teach that such medicaments are suitable active agents for effectively reducing pain in an individual. The expected result would be an improved transdermal drug delivery system, used for the alleviation of pain.

* * * * *

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert *et al.* (WO 96/19205) as applied to claims 1-7 and 10-12 above and further in view of Franke *et al.* (WO 01/26637).

The teachings of Ebert *et al.* are discussed above. Ebert *et al.* do not teach an active agent being salicylic acid.

Franke *et al.* ('637) teach a transdermal therapeutic system for administering salicylic acid and/or acetylsalicylic acid. The system has a backing layer, an active ingredient reservoir attached thereto, a membrane which controls the administration of the active ingredient in the absence of other control mechanisms, an adhesive device for fixing the system onto the skin and a protective layer which can be detached before application (see Abstract). The concentration of salicylic acid and/or acetylsalicylic acid ranges between 5-75% (p. 6, 2nd paragraph); (Claim 16). ((This amount reads on Applicant's claimed range of from about 5% to about 40% by weight of salicylic acid (claim 9)). Furthermore, suitable amounts could be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The prior art expressly teaches administration of the same active agent - saclicylic acid, employed for the same purpose (i.e., treat pain) and used for the same field of endeavor (transdermal delivery) as that desired by Applicants.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate active agents, such as salicylic acid as taught by Franke *et al.* within the transdermal device of Ebert *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Franke *et al.* teach pain-relieving medicaments, such as salicylic acid, administered through a transdermal therapeutic system to alleviate pain.

The expected result would be a highly effective transdermal therapeutic system, used to deliver medicaments, particularly for the reduction of pain to a subject in need thereof.

* * * * *

Response to Arguments

Applicant's arguments filed 27 April 2010 have been fully considered but were not found to be persuasive.

- **Rejection under 35 U.S.C. §103(a) over Ebert ('205) in view of Chiang ('468) & Min ('587):**

Applicant argued, " The claimed design provides an advantage in using fewer parts than required by Ebert, in particular avoiding the adhesive overlay and the use of a peel seal disc that are central to Ebert's design."

This argument was not persuasive. The instant "comprising" claim language does not exclude the extra components, parts or features disclosed by Ebert. The claim language is open to the presence of additional features or components asides from those instantly recited. Hence, this would include the additional parts/features of the Ebert device. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003).

Applicant further argued, "Ebert's peel seal disc is a required cover over the agent permeable membrane and is removed as part of a subassembly with the release liner layer (Ebert, p. 6, lines 3-14). In contrast, the device of the invention...removes the need for a second membrane cover, represented by Ebert's peel seal."

Applicant's arguments were not deemed convincing. It is noted that the instant device does not need a second membrane covering. However, as noted above, the instant claim language does not limit or restrict the additional features disclosed by Ebert, including the peel seal of Ebert. While Applicants have amended claim 1 to recite a "single" liner covering said sealing surface, the Examiner points out that this added limitation introduces new matter into the claim language, as the specification does not support recitation of a "single" liner. See 112, 1st paragraph (new matter) rejection above.

Applicant argued, "Neither Chiang nor Min cures these defects in Ebert. Min teaches against the invention by requiring a drug-containing matrix formed in part by an adhesive polymer. Min provides no opening but requires the drug pass through the adhesive polymer containing matrix. Chiang similarly teaches against by requiring an adhesive be applied to a drug-containing matrix."

Applicant's arguments have been considered but were not rendered persuasive. It is agreed that there may be potential contact between the drug and the adhesive in Min and Chiang. However, it should be noted that these references were not relied upon for their structural design features but rather were relied upon for the general teaching that it is well known to one of ordinary skill in the art to employ the use of a polymeric thickening agents and solvents (dialkylene glycol alkyl ether) as disclosed by Chiang as well as for the use of an alkylene glycol

(propylene glycol) as disclosed by Min for incorporation into transdermal delivery devices. Since both of these references amply teach the inclusion of such ingredients in transdermal devices, they are sufficient to meet the requirements for the polymeric thickener and solvent components. One of ordinary skill in the art would be motivated to employ the thickeners and solvents of Min and Chiang based on the beneficial effects obtained therein (i.e., dissolution & thickening properties). Furthermore, the primary reference of Ebert is initially sufficient for all that it suggests and teaches to one of ordinary skill in the art and in particular, for the teaching of the structural elements of the device. As delineated above, the instant "comprising" claim language does not exclude the extra components, parts or features disclosed by Ebert. The claim language is open to the presence of additional features or components asides from those instantly recited and this would include the additional elements of Ebert.

- **Rejection under 35 U.S.C. §103(a) over Ebert ('205) in view of Toppo ('860):**

Applicant argued, "Toppo does not describe any patch or drug containing reservoir technology".

In response to applicant's argument that Toppo is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this instance, the secondary reference of Toppo is sufficient for all that it teaches. Namely, Toppo teaches the inclusion of active agents, such as salicylic acid for use in transdermal drug delivery devices and thus is applicable for the

same technology (i.e., skin treating devices) as is instantly desired. Thus, there is ample motivation to apply the teachings of Toppo with Ebert. The primary reference of Ebert is initially sufficient for all that it suggests and teaches to one of ordinary skill in the art, and in particular, for the teaching of the structural elements of the device. As discussed above, the present claim language is open to the presence of additional features or components asides from those instantly recited, including the additional parts/elements of Ebert.

- **Rejection under 35 U.S.C. §103(a) over Ebert ('205) in view of Frankie ('637):**

Applicant argued, "Franke does not cure the defects of Ebert. Similar to the disclosure of Min and Chiang, Franke describes attaching a drug-containing polymer matrix layer by means of an adhesive material on the matrix alone or in combination with a 'special adhesive device' which would comprise the same materials as used for the polymer matrix."

The Examiner was not persuaded by these arguments because, as delineated above with respect to Chiang and Min, the Franke reference also was not relied upon for the teaching of a specific structural design but rather for the demonstration that it is common practice for one of ordinary skill in the art to employ active agents, such as salicylic acid for use in transdermal applications. Since Franke recognizes that salicylic is a suitable medicament for use in their invention and recognize that salicylic acid can be administered via transdermal means to achieve therapeutic results, the reference is sufficient to meet the claim requirements, absent a showing of evidence to the contrary. Ample motivation has been supplied by the secondary reference of Franke to be combined with the teachings of Ebert. Moreover, the primary reference of Ebert is initially sufficient for all that it suggests and teaches to one of ordinary skill in the art, and in

particular, for the teaching of the structural elements of the device. As discussed above, the present claim language is open to the presence of additional features or components asides from those instantly recited, including the additional parts/elements of Ebert. While Applicants have amended claim 1 to recite a "single" liner covering said sealing surface, the Examiner points out that this added limitation introduces new matter into the claim language, as the specification does not support recitation of a "single" liner. See 112, 1st paragraph (new matter) rejection above. The instant claims which utilize open-ended "comprising" language, do not preclude the additional elements or features contained in the device of Ebert.

It is suggested that the instant claims utilize closed-ended transitional language (*i.e.*, "consisting of") in order to avoid the additional elements, features or layers disclosed in the art.

The rejections of record have been maintained.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

August 16, 2010